

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Edward B. Zalenski et al.

Confirmation No. 5023

Application No. 10/750,173

Art Unit: 3733

Filed: December 31, 2003

Examiner: Annette R. Reimers

For: INSERTER INSTRUMENT AND IMPLANT
CLIP

Mail Stop After Final
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

In response to the Final Office Action dated March 7, 2007, Applicants request a pre-appeal brief review. No amendments are being filed with this request. This request is being filed with a notice of appeal. This review is requested for the reasons stated in the attached sheets.

Dated: August 6, 2007

Respectfully submitted,

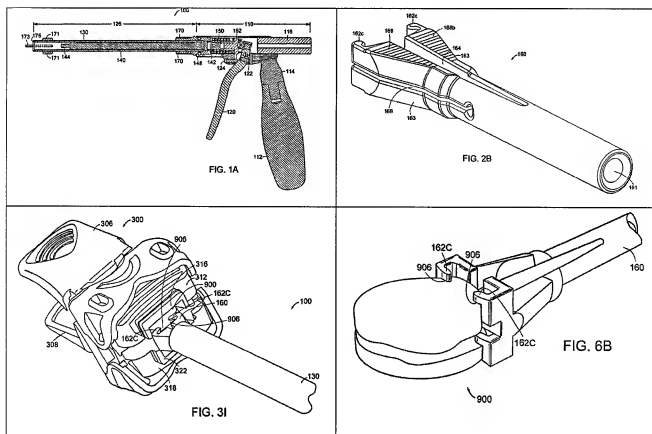


Ronald E. Cahill, Reg. No. 38,403
Attorney For Applicants
NUTTER MCCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
Tel. (617) 439-2782
Fax (617) 310-9782

REASONS FOR THE REQUESTED REVIEW

Introduction

The systems and methods described in the pending application relate to a device for implanting an implant, particularly, a multi-piece spinal disc prosthesis that can be provided inside a clip. Figure 1A below illustrates one embodiment of the implantation device. On its distal end, the device has a “grabber” (one embodiment of which is illustrated in isolation in Figure 2B, below). The distal end of the device is shown in Figure 3I below, engaged to a spinal disc prosthesis that has been enclosed within a clip to hold its components in a proper orientation for grabbing by the implantation device and for implantation. In Figure 6B, the clip has been removed and the distal end of the device is shown “grabbing” the multi-piece spinal disc prosthesis – now ready for implantation.



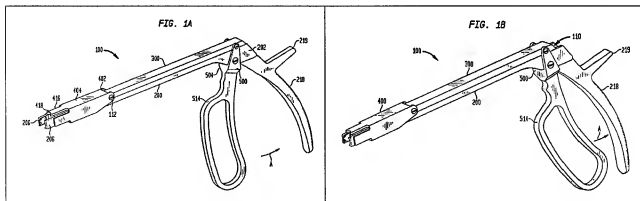
In the illustrated embodiment, squeezing the trigger causes the inner shaft carrying the grabber to move distally with respect to the outer sleeve, and allows the grabber to open. The grabber is engaged to the prosthesis while the prosthesis parts are held steady within the clip, and the trigger is released causing the inner shaft and grabber to retract distally into the outer sleeve.

Inner surfaces on the outer sleeve (the “retaining element”) push on outer sides of the grabber to cause it to close on the prosthesis as the trigger is released and the inner shaft is retracted. The elements of claim 1 can readily be understood in light of this illustrative example.

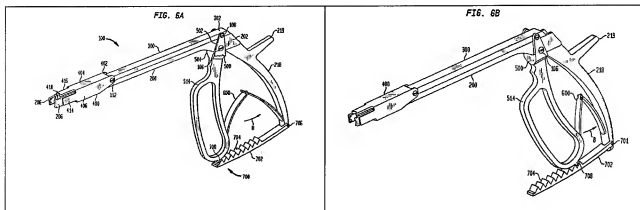
Background of the Art

Claims 1-7, 9, 11-13, and 15 stand rejected under 35 U.S.C. 102 as anticipated by Markworth (US 2003-0199872). The remaining claims (8, 10, 14 and 16-30) have been withdrawn as restricted (including dependent claims from claim 1 that recite features of the grabber).

Markworth provides an orthopedic device for urging a spinal fixation rod into a slot in the head of a pedicle screw. Markworth has a handle 218 is fixedly attached to a body 200. [Para. 44.] A trigger 500 connects to a slide 300 to provide sliding motion of the side on the body 200. [Para. 48.] A sleeve 400 is connected to the distal end of slide 300. [Para. 50.] In use, fingers 206 provided on the distal end of body 200 engage or grip the rod-receiving head of a pedicle screw. The trigger 500 is then squeezed toward the handle 218, as illustrated in Figures 1A and 1B below, so that slide 300 slides distally on body 200, pushing sleeve 400 distally, which in turn pushes the spinal fixation rod into the head of the pedicle screw. [Para. 51.]



As further illustrated in Figures 6A and 6B, a spring 600 and ratchet 700 are provided to bias the trigger 500 to its “unpulled” position in which the sleeve 400 is retracted:



Markworth Does Not Disclose the Features of Claim 1

Markworth is directed to a different problem – and works in a diametrically opposed manner to claim 1. As a result, Markworth’s structure is diametrically opposed to the recitations of claim 1. The Examiner’s anticipation case for claim 1 in the Final Office Action is as follows:

<i>Claim 1 Element:</i>	<i>Correspondence to Markworth per the Examiner:</i>
i) a frame having a trigger mechanism;	“a frame having a trigger mechanism, 514,”
ii) an outer sleeve mechanically coupled to the frame;	“an outer sleeve, 400, mechanically coupled to the frame,”
iii) an inner shaft having a grabber for mechanically engaging an implant, the inner shaft slidably disposed along a major axis of the inner shaft within the outer sleeve, whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant; and	“an inner shaft, 300, having a grabber, 206, for mechanically engaging an implant,” “wherein the inner shaft is slidably disposed along a major axis of the inner shaft within the outer sleeve,” “whereby actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant, and”
iv) a retaining element for directing the grabber toward a closed position whereby the grabber is substantially contained within the outer sleeve when the trigger is released.	a retaining spring element, 600, for directing the grabber toward a closed position, whereby the grabber is substantially contained within the outer sleeve when the trigger is released (see figures 6A, 6B, 7A and 7B).

Because the intended function of Markworth is so different from the claimed device, its structure is so different as to be exactly the opposite of the claimed configuration – making anticipation by Markworth impossible. Not only must “each and every element as set forth in the claim” be found in the prior art reference for anticipation to lie, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), but the elements

must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990); *See, also*, MPEP § 2131. The elements of Markworth are not so arranged.

In element (ii), the claim requires that the outer sleeve be mechanically coupled to the frame – the cited sleeve 400 in Markworth is not mechanically coupled to the frame, but rather is connected to the distal end of the slide 300 for sliding movement. [Para. 48.] The Examiner refers to this slide 300 as the “inner shaft” of the claims – not the frame – which would presumably correspond to body 200 in the Examiner’s scheme. Accordingly, this claim element is not met as the outer sleeve is not mechanically coupled to the frame.

In element (iii), the claim requires that the inner shaft have the grabber – the cited “grabber” 206 in Markworth is not on the “inner shaft” (slide 300, according to the Examiner). Rather, fingers 206 of Markworth (said to correspond to the “grabber”) extend from the distal end of the body 200. [Para. 42.] The only element provided on the “inner shaft” 300 is the “outer sleeve” 400 – which does not “grab” anything, but rather pushes on a spinal fixation rod. Accordingly, this claim element is not met as “inner shaft” 300 does not have a “grabber” 206.

The claim goes on to expressly state that the inner shaft (slide 300, according to the Examiner) is slidably disposed within the outer shaft (sleeve 400, according to the Examiner). Markworth does not disclose such a relationship, the sleeve 400 is pivotally connect to the distal end of the slide 300 – it does not and cannot slide with respect to it. [Para. 50.] Accordingly, this portion of the claim element is not met as the “inner shaft” 300 does not slidably disposed within “outer sleeve” 400.

Still further in element (iii), the claim requires that actuation of the trigger extends the grabber from the outer sleeve to thereby release the implant. First, squeezing the trigger 514 in Markworth does not move the grabber (fingers 206) at all. The position of the fingers 206 in Markworth is fixed by virtue of their fixed relationship on the distal end of the body 200 – there is no movement at all, much less extension. Second, squeezing the trigger in Markworth pushes sleeve 400 over fingers 206 – rather than being configured to extend the grabber outside out of the outer sleeve upon actuation, Markworth does the opposite of the claim recitation and pushes

the sleeve 400 over the fingers 206 when the trigger is actuated. Third, actuating the trigger in Markworth does not “thereby release the implant” – it does nothing to relationship between the grabber and the implant. In Markworth, a force is applied to the body 200 of Markworth to insert the implant between fingers 206 – “the fingers 206 continue to grip” the implant as the spinal fixation rod is oriented, then, after the rod is placed, the user releases the grip of the “grabber” by rotating the instrument in its entirety. [Para. 51.] Again, this recited feature of element (iii) is not met by Markworth – Markworth provides the opposite.

Turning to element (iv), when the claimed trigger is released, a retaining element directs the grabber toward a closed position whereby the grabber is substantially within the outer sleeve. Again, Markworth discloses the exact opposite. Referring to the very Figures cited by the Examiner, it is clear that releasing the trigger 500 (shown released, for example, in Figure 6A above) results in the fingers 206 (which never change their position in response to the trigger) being extended outward – not within – sleeve 400.

At every turn, Markworth discloses, teaches and suggests a structure that is the diametric opposite to that recited. Under these circumstances there can be no anticipation.

Claims 3, 5, 6, 12 and 15 are further patentable over Markworth as described at pages 13-14 of Applicants’ Amendment in Response to Final Office Action.